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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,456	05/02/2001	Marie-Francoise Rosier-Montus	ST00015 US NP	1457
5487 ROSS J. OEHL	7590 07/31/200° .ER		EXAM	IINER
SANOFI-AVEI 1041 ROUTE 2	NTIS U.S. LLC		SULLIVAN	, DANIEL M
MAIL CODE:		•	ART UNIT	PAPER NUMBER
BRIDGEWATI	ER, NJ 08807		1636	
	•			<b>.</b>
			NOTIFICATION DATE	DELIVERY MODE
	•		07/31/2007	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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USPatent.E-Filing@sanofi-aventis.com andrea.ryan@sanofi-aventis.com

	Application No.	Applicant(s)		
	09/846,456	ROSIER-MONTUS ET AL.		
Office Action Summary	Examiner	Art Unit		
	Daniel M. Sullivan	1636		
The MAILING DATE of this communication app Period for Reply	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. lely filed the mailing date of this communication. (35 U.S.C. § 133).		
Status		,		
1) Responsive to communication(s) filed on 12 Ju				
·—	action is non-final.			
3) Since this application is in condition for allowan				
closed in accordance with the practice under E	x parte Quayle, 1955 C.D. 11, 45	33 O.G. 213.		
Disposition of Claims				
4) Claim(s) <u>1,3,7-12,33-36 and 57-60</u> is/are pendi				
4a) Of the above claim(s) is/are withdraw	vn from consideration.			
5) Claim(s) is/are allowed.				
6)  Claim(s) <u>1,3,33-36 and 57-60</u> is/are rejected.				
7)⊠ Claim(s) <u>7-12</u> is/are objected to. 8)□ Claim(s) are subject to restriction and/or	election requirement			
are subject to restriction under	oloollon roquiromoni.			
Application Papers				
9) The specification is objected to by the Examine				
10)☐ The drawing(s) filed on is/are: a)☐ acce				
Applicant may not request that any objection to the				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
The factor of declaration is objected to by the Ex	arminer. Note the attached Office	Action of form F 10-132.		
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:				
1. Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
	·			
Attachment(s)				
1) Notice of References Cited (PTO-892)	4) Interview Summary Paper No(s)/Mail Da	(PTO-413) ate		
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	5) Notice of Informal P 6) Other: See Continue	atent Application		

Continuation of Attachment(s) 6). Other: SEQUENCE SEARCH RESULTS 09/846,456.

This Office Action is a reply to the Paper filed 12 July 2007 in response to the Non-Final Office Action mailed 14 February 2007. Claims 1-3, 5-14, 33-38, 57-60 were considered in the 14 February Office Action. Claims 2, 5, 6, 37 and 38 were cancelled in the 12 July Paper. Claims 1, 3, 7-12, 33-36 and 57-60 are pending and under consideration. Finality of the previous Office Action is withdrawn in view of the new grounds for rejection set forth herein below.

Response to Amendment and Arguments

Rejection of claims 2, 5, 6, 37 and 38 is rendered moot by the cancellation thereof.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in reciting, "ranging from nucleotide 1 at position -1" is withdrawn in view of the claim amendment.

New Grounds

Claim Objections

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. Claim 57 is directed to the isolated nucleic acid of claim 1, comprising at least 20 consecutive nucleotides of the sequence SEQ ID NO: 3 or the complement of SEQ ID NO: 3. Claim 1 is directed to an isolated nucleic acid comprising 500 or more consecutive nucleotides of SEQ ID NO: 1 or the complement of SEQ ID NO: 1.

As shown in the alignment of SEQ ID NO: 1 and SEQ ID NO: 3 attached hereto (us-09-846-456a-1.rnpbm, RESULT 7; page 8), SEQ ID NO: 3 comprises all but the final 338 bases of SEQ ID NO: 1. Therefore, any sequence comprising 500 or more consecutive nucleotides of SEQ ID NO: 1 must, at a minimum, comprise 162 bases of SEQ ID NO: 3. Therefore, all sequences within the scope of claim 1 must comprise more than 20 bases of SEQ ID NO: 3 and, consequently, claim 57 fails to further limit the subject matter of claim 1.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 33-36 and 57-60 are rejected under 35 U.S.C. 102(a) as being anticipated by NCBI Entrez Nucleotide Database entry AC012230.2 (19 November 1999), http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?val=6454033, downloaded 25 July 2007 as evidenced by Osoegawa et al. (2001) *Genome Res.* 11:483-496.

Claim 1 is directed to an isolated nucleic acid comprising a polynucleotide having 500 or more consecutive nucleotides of the nucleotide sequence SEQ ID NO: 1 and claim 3 is directed

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to an isolated nucleic acid comprising a polynucleotide having at least 200 consecutive nucleotides of the sequence SEQ ID NO: 3. Claim 57 is directed to the nucleic acid of claim 1, wherein the nucleic acid comprises at least 20 consecutive nucleotides of SEQ ID NO: 3.

The AC012230 entry teaches a nucleic acid comprising a 540 base sequence that is identical to nucleotides 2130-2670 of SEQ ID NO: 1 and 3. (See the alignment of SEQ ID NO: 3 with the AC012230 entry on the attached sequence search results (us-09-846-456a-3 oli.rge, RESULT 11). Note that the sequence at nucleotides 2130-2670 of SEQ ID NO: 1 is identical to the sequence of SEQ ID NO: 3 (see us-09-846-456a-1 rnpbm, RESULT 7; page 8 of the attached sequence search). Also note that the alignment on the sequence search is numbered according to version 3 of the AC012230 entry while the cited art is version 2 (i.e., AC012230.2). The corresponding sequence is begins at 2703 and continues through 3243 of the AC012230.2 sequence.

The AC012230 entry anticipates the limitations of the instant claims 1, 3 and 57. In addition, the AC012230 nucleic acid further comprises additional sequence which is "of interest" according to the limitations of claim 33 and would additionally comprise sequence that is in the sense and antisense orientation with respect to the promoter comprised by the nucleic acid, as well as sense and antisense sequences of interest comprised by the BAC vector itself, according to the limitations of claim 34. Claim 58 recites that the isolated nucleic acid further comprises 35 or more consecutive nucleotides of SEQ ID NO: 5 or the complement of SEQ ID NO: 5. This limitation is met by, for example, the sequence from 147555-147614 of the AC012230.2 sequence, which is 100% complementary to the sequence from nucleotide 100 to nucleotide 159 of SEQ ID NO: 5.

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Finally, the AC012230 entry teaches that the sequence is comprised in an RP11 clone (a.k.a., RPC-11, see under "DEFINITION"). Osoegawa et al. teaches that RPCI-11 is a BAC library. (See especially page 492, second sentence of the "DISCUSSION".) In view of the fact that nucleic acids in BAC libraries are comprised within vectors and propagated in bacteria, the cloning vector of claims 35 and 36 and isolated host cell of claims 59 and 60 are inherent to the teaching of the nucleic acid comprised in an RP11 clone as disclosed in the AC012230.

Database entry AC012230, as evidenced by Osoegawa et al., teaches all of the limitations of the instant claims. Therefore, the claims are anticipated by the prior art.

### Allowable Subject Matter

Claims 7-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-

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direct uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Daniel M. Sullivan, Ph.D.

Primary Examiner Art Unit 1636 SEQUENCE SEARCH RESULTS 09/846,456

#### us-09-846-456a-3.oli.rge

```
RESULT 11 ...
AC012230
LOCUS
             AC012230
                                                                      HTG 22-APR-2000
                                     175064 bp
                                                   DNA
                                                            linear
           Homo sapiens clone RP11-1M10, WORKING DRAFT SEQUENCE, 39 unordered
DEFINITION
             pieces.
             AC012230
ACCESSION
VERSION
             AC012230.3 GI:'7637254
KEYWORDS
             HTG; HTGS PHASE1; HTGS DRAFT.
SOURCE
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  ORGANISM
            Homo sapiens
             Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
             Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
             1 (bases 1 to 175064)
REFERENCE
  AUTHORS
             Birren, B., Linton, L., Nusbaum, C. and Lander, E.
  TITLE
             Homo sapiens, clone RP11-1M10
  JOURNAL
             Unpublished
REFERENCE
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             Birren, B., Linton, L., Nusbaum, C., Lander, E., Allen, N., Anderson, M.,
  AUTHORS
             Baldwin, J., Barna, N., Beckerly, R., Boguslavkiy, L., Boukhgalter, B.,
             Brown, A., Castle, A., Colangelo, M., Collins, S., Collymore, A., Cooke, P., DeArellano, K., Dewar, K., Domino, M., Donelan, L., Doyle, M.,
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             Morrow, J., Naylor, J., Norman, C.H., O'Connor, T., O'Donnell, P., Peterson, K., Pollara, V., Riley, R., Roy, A., Santos, R., Severy, P., Stange-Thomann, N., Stojanovic, N., Subramanian, A., Talamas, J.,
             Tesfaye, S., Tirrell, A., Vassiliev, H., Vo, A., Wheeler, J., Wu, X.,
             Wyman, D., Ye, W.J., Zimmer, A. and Zody, M.
  TITLE
             Direct Submission
             Submitted (21-OCT-1999) Whitehead Institute/MIT Center for Genome
  JOURNAL
             Research, 320 Charles Street, Cambridge, MA 02141, USA
             On Apr 22, 2000 this sequence version replaced gi:6454033.
COMMENT
             All repeats were identified using RepeatMasker:
             Smit, A.F.A. & Green, P. (1996-1997)
             http://ftp.genome.washington.edu/RM/RepeatMasker.html
                 ----- Genome Center
                 Center: Whitehead Institute/ MIT Center for Genome Research
                 Center code: WIBR
                 Web site: http://www-seq.wi.mit.edu
                 Contact: sequence_submissions@genome.wi.mit.edu
                 ----- Project Information
                 Center project name: L2510
                 Center clone name: 1_M_10
             ----- Summary Statistics
                 Sequencing vector: M13; M77815; 100% of reads
                 Chemistry: Dye-terminator Big Dye; 100% of reads
                 Assembly program: Phrap; version 0.960731
                 Consensus quality: 117571 bases at least Q40
                 Consensus quality: 145749 bases at least Q30
                 Consensus quality: 160940 bases at least Q20
                 Insert size: 185000; agarose-fp
                 Insert size: 171264; sum-of-contigs
                 Quality coverage: 2.9 in Q20 bases; agarose-fp
                 Quality coverage: 3.2 in Q20 bases; sum-of-contigs
             * NOTE: This is a 'working draft' sequence. It currently
             * consists of 39 contigs. The true order of the pieces
             * is not known and their order in this sequence record is
             * arbitrary. Gaps between the contigs are represented as
             * runs of N, but the exact sizes of the gaps are unknown.
             * This record will be updated with the finished sequence
             * as soon as it is available and the accession number will
             * be preserved.
                              1003: contig of 1003 bp in length
```

```
1004
           1103: gap of 100 bp
  1104
           2634: contig of 1531 bp in length
  2635
           2734: gap of 100 bp
           4415: contig of 1681 bp in length 4515: gap of 100 bp
  2735
  4416
           5785: contig of 1270 bp in length
  4516
  5786
           5885: gap of 100 bp
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  7880
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  9687
  9787
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 12354
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 25808
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109279
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117408
124080 -
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131382
138060
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                         145591: gap of 100 bp
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                         157391: contig of 11800 bp in length
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                157392
                         157491: gap of 100 bp
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                      68538. .71458
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                     clone_end:SP6
                     vector side:left"
                          18.7%; Score 541; DB 2; Length 175064;
  Query Match
 Best Local Similarity 100.0%; Pred. No. 2.4e-294;
                                                    0; Indels
 Matches 541; Conservative
                                  0; Mismatches
                                                                   0; Gaps
         Qу
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Qу	2190	GTAAGATGTTCCTCTGGGGTCCTCTGAGGGACCTGGGGAGCTCAGGCTGGGAATCTCCAA	2249
Db	2963	GTAAGATGTTCCTCTCGGGTCCTCTGAGGGACCTGGGGAGCTCAGGCTGGGAATCTCCAA	3022
Qy .	2250	GGCAGTAGGTCGCCTATCAAAAATCAAAGTCCAGGTTTGTGGGGGGAAAACAAAAGCAGC	2309
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Qy .	2310	CCATTACCCAGAGGACTGTCCGCCTTCCCCTCACCCAGCCTAGGCCTTTGAAAGGAAAC	2369
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Db .	3143	AAAAGACAAGACAAAATGATTGGCGTCCTGAGGGAGATTCAGCCTAGAGCTCTCTCCC	3202
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Qy	2670	C 2670	
Db	3443	C 3443	

## 47404-848-A F6A-N. \$1900#

```
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LOCUS
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                                            175064 bp
                                                             DNA
                                                                       linear HTG 22-APR-2000
DEFINITION Homo sapiens clone RP11-1M10, WORKING DRAFT SEQUENCE, 39 unordered
               pieces.
ACCESSION
               AC012230
VERSION
               AC012230.3 GI:7637254
KEYWORDS
               HTG; HTGS PHASE1; HTGS DRAFT.
SOURCE
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  ORGANISM Homo sapiens
               Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
               Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
               1 (bases 1 to 175064)
REFERENCE
               Birren, B., Linton, L., Nusbaum, C. and Lander, E.
  AUTHORS
  TITLE
               Homo sapiens, clone RP11-1M10
  JOURNAL
               Unpublished
REFERENCE
               2 (bases 1 to 175064)
               Birren, B., Linton, L., Nusbaum, C., Lander, E., Allen, N., Anderson, M., Baldwin, J., Barna, N., Beckerly, R., Boguslavkiy, L., Boukhgalter, B.,
  AUTHORS
               Brown, A., Castle, A., Colangelo, M., Collins, S., Collymore, A., Cooke, P., DeArellano, K., Dewar, K., Domino, M., Donelan, L., Doyle, M., Ferreira, P., FitzHugh, W., Forrest, C., Funke, R., Gage, D.,
               Galagan, J., Gardyna, S., Grant, G., Hagos, B., Heaford, A., Horton, L.,
               Howland, J.C., Johnson, R., Jones, C., Kann, L., Karatas, A., Klein, J.,
               Lehoczky, J., Lieu, C., Locke, K., Macdonald, P., Marquis, N.,
               McEwan, P., McGurk, A., McKernan, K., McLaughlin, J., Meldrim, J.,
               Morrow, J., Naylor, J., Norman, C.H., O'Connor, T., O'Donnell, P., Peterson, K., Pollara, V., Riley, R., Roy, A., Santos, R., Severy, P.,
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Stange-Thomann, N., Stojanovic, N., Subramanian, A., Talamas, J.,
            Tesfaye, S., Tirrell, A., Vassiliev, H., Vo, A., Wheeler, J., Wu, X.,
            Wyman, D., Ye, W.J., Zimmer, A. and Zody, M.
 TITLE
            Direct Submission
  JOURNAL
            Submitted (21-OCT-1999) Whitehead Institute/MIT Center for Genome
            Research, 320 Charles Street, Cambridge, MA 02141; USA
COMMENT
            On Apr 22, 2000 this sequence version replaced gi:6454033.
            All repeats were identified using RepeatMasker:
            Smit, A.F.A. & Green, P. (1996-1997)
            http://ftp.genome.washington.edu/RM/RepeatMasker.html
                  ----- Genome Center
                Center: Whitehead Institute/ MIT Center for Genome Research
                Center code: WIBR
                Web site: http://www-seq.wi.mit.edu
                {\tt Contact: sequence\_submissions@genome.wi.mit.edu}
                 ----- Project Information
                Center project name: L2510
                Center clone name: 1_M_10
               ----- Summary Statistics
                Sequencing vector: M13; M77815; 100% of reads
                Chemistry: Dye-terminator Big Dye; 100% of reads
                Assembly program: Phrap; version 0.960731
                Consensus quality: 117571 bases at least Q40
                Consensus quality: 145749 bases at least Q30
                Consensus quality: 160940 bases at least Q20
                Insert size: 185000; agarose-fp
                Insert size: 171264; sum-of-contigs
                Quality coverage: 2.9 in Q20 bases; agarose-fp
                Quality coverage: 3.2 in Q20 bases; sum-of-contigs
            * NOTE: This is a 'working draft' sequence. It currently
            * consists of 39 contigs. The true order of the pieces
            * is not known and their order in this sequence record is
              arbitrary. Gaps between the contigs are represented as
              runs of N, but the exact sizes of the gaps are unknown.
            * This record will be updated with the finished sequence
            * as soon as it is available and the accession number will
              be preserved.
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Db

Qу

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Οv

Db

Qу

Db

Db

Qу

Db

#### us-09-846-456a-1.rnpbm

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; Patent No. US20020146792A1
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  APPLICANT: Rosier, Marie
  APPLICANT: Prades, Catherine
  APPLICANT: Lemoine, Cendrine
  APPLICANT: Naudin, Laurent
  APPLICANT:
          Denefle, Patrice
  APPLICANT: Duverger, Nicolas
  APPLICANT: Brewer, Bryan
  APPLICANT: Remaley, Alan
  APPLICANT: Fojo, Silvia
  TITLE OF INVENTION: Regulatory Nucleic Acid for the ABC1 Gene, Molecules Modifying Its
  TITLE OF INVENTION: Activity and Therapeutic Uses
  FILE REFERENCE: 3806.0505
  CURRENT APPLICATION NUMBER: US/09/846,456
  CURRENT FILING DATE: 2001-05-02
  PRIOR APPLICATION NUMBER: US 60/201,280
  PRIOR FILING DATE: 2000-05-02
  NUMBER OF SEQ ID NOS: 20
  SOFTWARE: PatentIn version 3.0
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  TYPE: DNA
  ORGANISM: Homo sapiens
US-09-846-456-3
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